

DRUG DISCOVERY

FDA approved drugs – July 2013

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Received 04 August; accepted 20 August; published online 01 September; printed 16 September 2013

1. BRISDELLE (LOW-DOSE PAROXETINE MESYLATE)

1.1. Company

Noven Pharmaceuticals; Approved by July 2013

1.2. Treatment Area

Vasomotor symptoms of menopause

1.3. General Information

Brisdelle is specifically indicated for the treatment of moderate to severe vasomotor symptoms associated with menopause. It is supplied as a capsule for oral administration. The recommended dose is 7.5 mg once daily with or without food.

1.4. Mechanism of Action

Brisdelle is a low-dose formulation of paroxetine mesylate, a selective serotonin reuptake inhibitor. It is not an estrogen, and its mechanism of action for the treatment of VMS is unknown.

1.5. Side Effects

Adverse events associated with the use of Brisdelle includes: headache, fatigue, nausea/vomiting

2. INJECTAFER (FERRIC CARBOXYMALTOSE INJECTION)

2.1. Company

Luitpold Pharmaceuticals; Approved by July 2013

2.2. Treatment Area

Iron deficiency anemia

2.3. General Information

Injectafer (ferric carboxymaltose injection) is used as an iron replacement product. It is an iron carbohydrate complex. It is specifically indicated for the treatment of iron deficiency anemia in adults who have intolerance to oral iron or have had unsatisfactory response to oral iron or adults who have non-dialysis dependent chronic kidney disease. It is supplied as a solution for intravenous administration. The recommended dosing is as follows: For patients weighing 50 kg (110 lb) or more: Give Injectafer in two doses separated by at least 7 days. Give each dose as 750 mg for a total cumulative dose not to exceed 1500 mg of iron per course. For patients weighing less than 50 kg (110 lb): Give Injectafer in two doses separated by at least 7 days. Give each dose as 15 mg/kg body weight for a total cumulative dose not to exceed 1500 mg of iron per course.

2.4. Mechanism of Action

Injectafer (ferric carboxymaltose injection) is a colloidal iron (III) hydroxide in complex with carboxymaltose, a carbohydrate polymer that releases iron.

2.5. Side Effects

Adverse events associated with the use of Injectafer includes: nausea, hypertension, flushing, hypophosphatemia, dizziness

3. FETZIMA (LEVOMILNACIPRAN)

3.1. Company

Forest Labs; Approved by July 2013

3.2. Treatment Area

Major depressive disorder

3.3. General Information

Fetzima is specifically indicated for the treatment of Major Depressive Disorder. It is supplied as a capsule for oral administration. The recommended dose is 40 mg to 120 mg once daily with or without food. Initiate dose at 20 mg once daily for 2 days and then increase to 40 mg once daily. The dose should

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Drug discovery, 2013, 5(15), 20-22,

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be increased in increments of 40 mg at intervals of 2 or more days. The maximum recommended dose is 120 mg once daily. The capsules should be swallowed whole.

3.4. Mechanism of Action

Fetzima (levomilnacipran) is an extended release selective norepinephrine and serotonin reuptake inhibitor. The exact mechanism of the antidepressant action of levomilnacipran is unknown, but is thought to be related to the potentiation of serotonin and norepinephrine in the central nervous system, through inhibition of reuptake at serotonin and norepinephrine transporters. Non-clinical studies have shown that levomilnacipran is a potent and selective serotonin and norepinephrine reuptake inhibitor (SNRI).

3.5. Side Effects

Adverse events associated with the use of Fetzima includes: nausea, constipation, hyperhidrosis, heart rate increase, erectile dysfunction, tachycardia, vomiting, palpitations

4. ZUBSOLV (BUPRENORPHINE AND NALOXONE)

4.1. Company

Orexo AB, Approved by July 2013

4.2. Treatment Area

Maintenance treatment of opioid dependence

4.3. General Information

Zubsolv is a sublingual tablet formulation of buprenorphine, an opioid analgesic, and naloxone, an opioid antagonist. It was designed to counteract the high effect that may arise following the intravenous injection of a dissolved tablet. Combining buprenorphine and naloxone in a single tablet reduces the risk of intravenous abuse. It is specifically indicated for the maintenance treatment of opioid dependence and should be used as part of a complete treatment plan to include counseling and psychosocial support. It is supplied as a tablet for sublingual administration. The recommended target dosage of Zubsolv sublingual tablet is 11.4 mg/2.8 mg buprenorphine/naloxone/day (two 5.7/1.4 mg tablets) as a single daily dose. The dosage of Zubsolv should be progressively adjusted in increments/decrements of 1.4 mg/0.36 mg or 2.8 mg/0.72 mg buprenorphine/naloxone to a level that holds the patient in treatment and suppresses opioid withdrawal signs and symptoms.

4.4. Mechanism of Action

Zubsolv contains buprenorphine and naloxone. Buprenorphine is a partial agonist at the mu-opioid receptor and an antagonist at the kappa-opioid receptor. Naloxone is a potent antagonist at mu-opioid receptors and produces opioid withdrawal signs and symptoms, if administered parenterally, in individuals physically dependent on full opioid agonists.

4.5. Side Effects

Adverse effects associated with the use of Zubsolv includes: headache, nausea, vomiting, hyperhidrosis, constipation, insomnia, pain, peripheral edema

5. LO MINASTRIN, (NORETHINDRONE ACETATE, ETHINYL ESTRADIOL, FERROUS FUMARATE)

5.1. Company

Warner Chilcott, Approved by July 2013

5.2. Treatment Area

Prevention of pregnancy

5.3. General Information

Lo Minastrin Fe is specifically indicated for use by women to prevent pregnancy. It is supplied as tablets for oral administration. Lo Minastrin Fe administration should begin on Day 1 of the menstrual cycle (that is, the first day of her menstrual bleeding). One blue tablet should be taken daily for 24 consecutive days, followed by one white tablet daily for 2 consecutive days, followed by one brown tablet daily for 2 consecutive days. To achieve maximum contraceptive effectiveness, Lo Minastrin Fe must be taken exactly as directed. The blue tablet should be chewed and swallowed. The patient should drink a full glass (8 ounces) of water immediately after chewing and swallowing the blue tablet. The white tablet and the brown tablet are swallowed.

5.4. Mechanism of Action

Lo Minastrin Fe (norethindrone acetate and ethinyl estradiol chewable tablets, ethinyl estradiol tablets and ferrous fumarate tablets) is an estrogen/progestin combined oral contraceptive. It works primarily by suppressing ovulation. Other possible mechanisms may include cervical mucus changes that inhibit sperm penetration and endometrial changes that reduce the likelihood of implantation.

5.5. Side Effects

Adverse events associated with the use of Lo Minastrin Fe includes: nausea/vomiting, headache, bleeding irregularities, dysmenorrhea, weight change, breast tenderness, acne, abdominal pain, anxiety, depression

6. GILOTRIF (AFATINIB)

6.1. Company

Boehringer Ingelheim; Approved by July 2013

6.2. Treatment Area

Metastatic non-small cell lung cancer with EGFR mutations

6.3. General Information

Gilotrif (afatinib) is specifically indicated for the first-line treatment of patients with metastatic non-small cell lung cancer whose tumors have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations as detected by an FDA-approved test. It is supplied as a tablet for oral administration. The recommended dose is 40 mg orally once daily until disease progression or no longer tolerated by the patient. It should be taken at least 1 hour before or 2 hours after a meal.

6.4. Mechanism of Action

Gilotrif covalently binds to the kinase domains of EGFR (ErbB1), HER2 (ErbB2), and HER4 (ErbB4) and irreversibly inhibits tyrosine kinase autophosphorylation, resulting in downregulation of ErbB signaling.

6.5. Side Effects

Adverse events associated with the use of Gilotrif includes: diarrhea, rash/dermatitis, acneiform, stomatitis, paronychia, dry skin, decreased appetite, pruritus